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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/332,522	06/14/1999	MICHAEL R. COSTA	7326-101	3045

23500 7590 04/22/2003

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EXAMINER

SHUKLA, RAM R

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 04/22/2003

32

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/332,522

Applicant(s)

COSTA ET AL.

Examiner

Ram R. Shukla

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 8-5-02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,13,14,16-18,22-28 and 34-36 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

- 6) ☒ Claim(s) 1,2,13,14,16-18,22,23,25-28 and 34-36 is/are rejected.

- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 26. 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on **8-5-02** has been entered.
2. Amendments filed 1-24-02 and 8-05-02 have been entered.
3. Claims 3, 4, 6, 8-11 and 15 have been canceled.
4. Claim 1,2,13,14,16-18,22-28 and 34-36 are pending.

### ***Specification***

5. The amendment filed 8-5-02, 1-24-03, and 1-28-03 are objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

It is noted that SEQ ID NO 94 and 95 were added to the specification first in claim 1 and then in the sequence listing. Applicants have asserted that these sequences have been incorporated by reference to page 44, lines 32-36 and page 64 lines 5-6. These sections of the specification disclose Genbank accession numbers GI1559384 and GI3875380. However, information in Genbank is not permanent and is updated frequently. In the instant case, sequence revision history of GI3875380 indicates that it was revised 24 times since it was first deposited (see attached printout of the locus CAA87777). Applicants have not provided any evidence as to which of these 24 sequences the sequence submitted in SEQ ID NO 94 corresponds to. Applicants are required to provide evidence that the sequence submitted in SEQ ID NO 94 is the sequence that was present in the Genbank at the time Genbank was accessed and the sequence was used as

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disclosed in the specification. Regarding sequence of SEQ ID NO 95, it is noted that the GI1559384 is not a protein sequence, rather a nucleotide sequence (see attached print out for C11831. Therefore, there is no support for SEQ ID NO 95 in the specification. Additionally, GI1559384 has also been modified and there is no evidence to indicate whether the sequence in SEQ ID NO 95 is the same sequence that was accessed and used at the time of the invention.

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1,2, 13, 14, 16-18 and 34-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is noted that SEQ ID NO 94 and 95 were added to the specification first in claim 1 and then in the sequence listing. Applicants have asserted that these sequences have been incorporated by reference to page 44, lines 32-36 and page 64 lines 5-6. These sections of the specification disclose Genbank accession numbers GI1559384 and GI3875380. However, information in Genbank is not permanent and is updated frequently. In the instant case, sequence revision history of GI3875380 indicates that it was revised 24 times since it was first deposited (see attached printout of the locus CAA87777). Applicants have not provided any evidence as to which of these 24 sequences the sequence submitted in SEQ ID NO 94 corresponds to. Applicants are required to provide evidence that

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the sequence submitted in SEQ ID NO 94 is the sequence that was present in the Genbank at the time Genbank was accessed and the sequence was used as disclosed in the specification. Regarding sequence of SEQ ID NO 95, it is noted that the GI1559384 is not a protein sequence, rather a nucleotide sequence (see attached print out for C11831. Therefore, there is no support for SEQ ID NO 95 in the specification. Additionally, GI1559384 has also been modified and there is no evidence to indicate whether the sequence in SEQ ID NO 95 is the same sequence that was accessed and used at the time of the invention.

Therefore, claims 1, 13 and 34-36 recite new matter.

8. Claim 22, 23 and 25-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide molecule that comprises the sequence of SEQ ID NO 1 and encodes the amino acid sequence of SEQ ID NO 2, does not reasonably provide enablement any other embodiment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification is not enabling for all the polynucleotides and host cells and method encompassed by the claimed invention because the specification only teaches the polynucleotide of SEQ ID NO 1 that encodes the polypeptide of SEQ ID NO 2. The issue is: any polynucleotides as disclosed claim 22 encode a functionally active polypeptide and the polypeptide will have at least 80% sequence identity with 1-1113 of SEQ ID NO 2. It is noted that the claimed polynucleotides would encompass those that encode a protein that has at least 20% amino acid difference compared to SEQ ID NO 2 in the region of AA 1-1113, which would mean a change of at least 220 amino acids. And such changes when evenly spread over the entire protein would alter the activity of the protein. While the claim recites a particular hybridization condition, that does teach as to what amino acids could be altered (up to 220) that will produce a functionally active protein. Additionally, what will be the function of such a functionally active SREBP. The specification does not teach how to make a protein that will have 20% amino acids changed and still retain function.

It is recognized in the prior art that the function of a protein depends on the sequence of its amino acids in a certain pattern, conformation of the protein due to the amino acid sequence, and the functional properties of the different parts of the protein (see second paragraph in Rudinger J in Peptide Hormones. Editor Parsons JA. Pages 1-7, 1976, University Park Press, Baltimore). Rudinger further add, "The significance of particular amino acids and sequences for different aspects of biological activity can not be predicted *a priori* but must be determined from case to case by painstaking experimental study" (see conclusion on page 6). The specification does not teach which changes in the nucleotide sequence of SEQ ID NO 1 would encode an amino acid sequences that would have at least 80% sequence identity with SEQ ID NO 2 and retain the biological activity of the SREBP. The specification does not teach how to use a nucleic acid that would have encoded a protein which was derived from the protein of SEQ ID NO 2 but did not have the function of the starting protein. Alternatively, the specification does not teach how would an artisan have made a polynucleotide that would have encoded a protein in which every other amino acids would have been changed but the protein would have retained the function of the starting protein. As set forth in *In re Fisher*, 166 USPQ 18 (CCPA 1970), compliance with 35 USC 112, first paragraph requires:

that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved.

It is noted that if an artisan was not able to make the polynucleotides encompassed by the claimed invention, artisan would not have been able to make the vector, host cell comprising the vector or produce protein from the host cells

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comprising the vector because the novelty of the invention will be the polynucleotides.

In summary, the specification is not enabling for the claimed polynucleotides commensurate with the scope of the claims and an artisan of skill would have required undue experimentation to make and use the claimed polynucleotides commensurate with the full scope of the claims because the specification does not provide sufficient guidance how to make and use the invention. Therefore, limiting the scope of the claimed invention to an isolated polynucleotide molecule that comprises the sequence of SEQ ID NO 1, a vector comprising the polynucleotide, a host cell comprising the vector and a method of producing the protein encoded by the polynucleotide from the host cell is proper.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-4, 6, 8-11, 13-18, and 34-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite because it is whether "that has been" refers to "C.elegans" or "claim 1". Using the term "wherein said C.elegans has been" will be remedial.

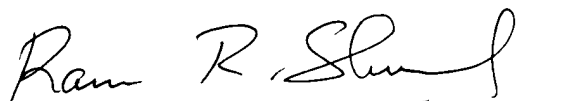
Claim 22 is indefinite because it is unclear as to what is meant by the term "(ab)" in line 2.

Claim 22 is also indefinite because the metes and bounds of the term "functionally active" are not clear. The specification does not clearly define what is encompassed by the term.

11. No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. The after-final fax number is (703) 87209307. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.

A handwritten signature in black ink, appearing to read "Ram R. Shukla", with a horizontal line extending from the end of the signature.

Ram R. Shukla, Ph.D.

Primary Examiner

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